

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

)
Tri-Cities Holdings LLC, Jane Doe)
Nos. 1, and John Does No. 1-5.)
)
Plaintiffs,)
) Case No. _____
)
)
)
Johnson City, Johnson City Board of)
Zoning Appeals, and Johnson City)
Planning Commission,)
)
Defendants.)

DECLARATION OF J. DAVID LENTZ, M.D.

I, J. David Lentz, MD do declare under penalty of perjury and if called as a witness would testify as follows:

1. I am over the age of 18 and a resident of Gwinnett County, Georgia. I have lived in Georgia for 20 years.

EDUCATIONAL BACKGROUND

2. I attended the Medical College of Georgia from 1971 to 1975 where I received a Doctorate in Medicine.

3. I have been a part owner and program physician of Crossroads Treatment Centers - a chain of nine opiate treatment programs (aka methadone clinics). Crossroads has provided treatment to thousands of opiate addicted people in Georgia, South Carolina, North Carolina, Tennessee and Virginia.

PROFESSIONAL BACKGROUD

4. This case involves a non-residential substance abuse program that is an Opiate Treatment Program ("OTP") that TCH intends to operate at 4 Wesley Court, Johnson City, Tennessee ("Proposed Location").

OPIOD DEPENDENCY AND TREATMENT

5. Opioid dependence is a medical diagnosis characterized by an individual's inability to stop using opioids (morphine, heroin, codeine, oxycodone, hydrocodone, etc.) even when objectively it is in his or her best interest to do so.

6. I would agree with the World Health Organization Expert Committee on Drug Dependence definition "dependence" as "[a] cluster of physiological, behavioral and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (or drugs) takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behavior. Determinants and problematic consequences of drug dependence may be biological, psychological or social, and usually interact".

strong desire or a sense of compulsion to take the drug; and the WHO and DSM-IV-TR clinical guidelines for a definite diagnosis of "dependence" require that three or more of the following six characteristic features be experienced or exhibited:

- a. A strong desire or sense of compulsion to take the drug;
- b. Difficulties in controlling drug-taking behavior in terms of its onset, termination, or levels of use;
- c. A physiological withdrawal state when drug use is stopped or reduced, as evidenced by: the characteristic withdrawal syndrome for the substance; or use of the same (or a closely related) substance with the intention of relieving or avoiding withdrawal symptoms;
- d. Evidence of tolerance, such that increased doses of the drug are required in order to achieve effects originally produced by lower doses;
- e. Progressive neglect of alternative pleasures or interests because of drug use, increased amount of time necessary to obtain or take the drug or to recover from its effects;

f. Persisting with drug use despite clear evidence of overtly harmful consequences, such as harm to the liver, depressive mood states or impairment of cognitive functioning.

7. Physical symptoms of withdrawal from opiates include, but are not limited to: Tremors; cramps; muscle and bone pain; chills; perspiration (sweating); priapism; tachycardia (rapid heart beat); itching; Restless Legs Syndrome; flu-like symptoms; Rhinitis (runny, inflamed nose); yawning; sneezing; vomiting; Diarrhea; weakness; Akathisia (a profoundly uncomfortable feeling of inner restlessness)

8. Psychological symptoms of withdrawal from opiates include, but are not limited to: Dysphoria; malaise; cravings; anxiety/panic attacks; paranoia; insomnia; dizziness; nausea; and, depression.

9. Depending on the quantity, type, frequency, and duration of opioid use, the physical withdrawal symptoms last for as little as forty-eight to seventy-two hours (for short-acting opioids such as hydromorphone [Dilaudid] and oxycodone after short duration lower-dose use), and as long as thirty to sixty days or more for long-acting opioids such as buprenorphine and methadone, respectively, after extended high-dose use.

10. Other rare but much more serious symptoms of opioid withdrawal include cardiac arrhythmias, strokes, seizures, dehydration and suicide attempts.

11. Opioid dependence is a complex health condition that often requires long-term treatment and care. The treatment of opioid dependence is important to reduce its health and social consequences and to improve the well-being and social functioning of people affected. The main objectives of treating and rehabilitating persons with opioid dependence are to reduce dependence on illicit drugs; to reduce the morbidity and mortality caused by the use of illicit opioids, or associated with their use, such as infectious diseases; to improve physical and psychological health; to reduce criminal behavior; to facilitate reintegration into the workforce and education system and to improve social functioning. The ultimate achievement of a drug-free state is the ideal and ultimate objective but this is unfortunately not feasible for all individuals with opioid dependence, especially in the short term.

12. As no single treatment is effective for all individuals with opioid dependence, diverse treatment options are needed, including psychosocial approaches and pharmacological treatment.

13. Relapse following detoxification alone is extremely common, and therefore detoxification rarely constitutes an adequate treatment of substance dependence on its own. However, it is a first step for many forms of longer-term abstinence-based treatment. Both detoxification with subsequent abstinence-

oriented treatment and substitution maintenance treatment are essential components of an effective treatment system for people with opioid dependence.

OPIOID-ADDICTED PERSONS ARE DISABLED

14. In my opinion, an opioid-addicted person suffers from a physical or mental impairment that substantially limits one or more of the following major life activities, including, without limitation, caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, speaking, breathing, learning, reading, concentrating, thinking, communicating, and working as well as the operation of several specified major bodily functions, including, without limitation, functions of the digestive, bowel, bladder, neurological, brain, respiratory, circulatory, and reproductive functions.

METHADONE MAINTENANCE TREATMENT

15. MMT (“Methadone Maintenance Treatment”), a form of opioid replacement therapy, reduces and/or eliminates the use of illicit opiates, the criminality associated with opiate use, and allows patients to improve their health and social productivity. In addition, enrollment in methadone maintenance has the potential to reduce the transmission of infectious diseases associated with opiate injection, such as hepatitis and HIV. The principal effects of methadone maintenance are to relieve narcotic craving, suppress the abstinence syndrome, and block the euphoric effects associated with opiates. Methadone maintenance has

been found to be medically safe and non-sedating. It is also indicated for pregnant women addicted to opiates. Methadone Maintenance Treatment is given to addicted individuals who feel unable to go the whole way and get clean. For those individuals who wish to completely move away from drugs, a methadone reduction program is indicated, where the individual is prescribed an amount of methadone which is titrated up until withdrawal symptoms subside, followed by a period of stability, the dose will then be gradually reduced until the individual is either free of the need for methadone or is at a level which allows a switch to a different opiate with an easier withdrawal profile, such a Suboxone.

EFFICACY OF METHADONE TO TREAT OPIOID DEPENDENCY

16. My personal experience treating thousands of opioid-addicted persons and, in addition, based upon reliable authorities in the field of addiction therapy, demonstrates that Methadone Maintenance Treatment is an effective treatment for heroin and prescription narcotic addiction when measured by the following parameters:

- A. Reduction in the use of illicit drugs;
- B. Reduction in criminal activity;
- C. Reduction in needle sharing;
- D. Reduction in HIV infection rates and transmission;
- E. Cost-effectiveness;
- F. Reduction in commercial sex work;
- G. Reduction in the number of reports of multiple sex partners;

- H. Improvements in social health and productivity;
- I. Improvements in health conditions;
- J. Retention in addiction treatment;
- K. Reduction in suicide;
- L. Reduction in lethal overdose.

17. My opinion on the effectiveness and benefits of Methadone Maintenance Treatment is based on my own personal experience treating more than 1,000 opiate-addicted persons in my medical practice and, in addition, is based upon the conclusions of reliable authorities in the field of addiction therapy and more specifically in the field of Methadone Maintenance Treatment.

18. For example, recent meta-analyses have supported the efficacy of methadone for the treatment of opioid dependence. These studies have demonstrated across countries and populations that methadone can be effective in improving treatment retention, criminal activity, and heroin use (Marsch LA. The Efficacy Of Methadone Maintenance Interventions In Reducing Illicit Opiate Use, HIV Risk Behavior And Criminality: A Meta-Analysis. *Addiction* 1998; 93(4):515-32.).

19. In addition, an overview of 5 meta-analyses and systematic reviews, summarizing results from 52 studies and 12,075 opioid-dependent participants, found that when Methadone Maintenance Treatment was compared with methadone detoxification treatment, no treatment, different dosages of methadone, buprenorphine maintenance treatment, heroin maintenance treatment, and L-a-

acetylmethadol (LAAM) maintenance treatment, Methadone Maintenance Treatment was more effective than detoxification, no treatment, buprenorphine, LAAM, and heroin plus methadone. High doses of methadone are more effective than medium and low doses (Amato L, Davoli M, Perucci C, Ferri M, Faggiano F, Mattick RP. An Overview Of Systematic Reviews Of The Effectiveness Of Opiate Maintenance Therapies: Available Evidence To Inform Clinical Practice And Research. *Journal of Substance Abuse Treatment* 2005;28(4):321-29.).

20. In another study, patients receiving Methadone Maintenance Treatment exhibit reductions in illicit opioid use that are directly related to methadone dose, the amount of psychosocial counseling, and the period of time that patients stay in treatment. Patients receiving methadone doses of 80 to 100 mg have improved treatment retention and decreased illicit drug use compared with patients receiving 50 mg of methadone (Simpson DD. Drug Treatment Evaluation Research In The United States. *Psychology of Addictive Behaviors* 1993;7(2):120-28.).

21. Patients' illicit opioid use declines, often dramatically, during methadone maintenance treatment. However, adequate methadone dosage and basic psychosocial services are essential for treatment effectiveness.

22. The daily oral administration of adequate dosages of methadone reduces the need for opioid-dependent individuals to inject drugs. By decreasing

injection drug use, Methadone Maintenance Treatment helps reduce the spread of diseases transmitted through needle sharing, such as human immunodeficiency virus (HIV) infection, hepatitis C virus (HCV), and other bloodborne infections

23. Patients are less likely to become involved in criminal activity while in methadone maintenance treatment.

24. Patients who remain in Methadone Maintenance Treatment for long periods of time are less likely to be involved in criminal activity than patients in treatment for short periods.

25. The availability of Methadone Maintenance Treatment in a community is associated with a decrease in that community's criminal activity, particularly theft.

26. The likelihood of becoming and remaining employed is increased for patients who participate in methadone maintenance treatment.

27. Patients receiving methadone maintenance who disengage from interactions with others who are actively using drugs are less likely to engage in these behaviors. In addition, reductions in alcohol and drug use result from the counseling services included in methadone maintenance treatment. When these services are specifically designed to reduce alcohol and other drug use, such reductions are likely.

28. Methadone is medically safe. Long-term Methadone Maintenance Treatment at doses of 80 to 120 mg per day is not toxic or dangerous to any organ system after continuous treatment for 10 to 14 years in adults and 5 to 7 years in adolescents.

DISTANCE IS A BARRIER TO TREATMENT

29. The distance that a patient must travel to a methadone treatment clinic is a tremendous barrier to treatment. My experience indicates that once a patient must drive more than 25 miles to the clinic, participation rates begin to fall significantly. For every patient that makes the commute, several are most likely foregoing treatment because they can't afford the time, money or energy.

30. Under the SAMSHA guidelines, almost all methadone treatment clinics that I am aware of allow a patient a take home only one dose per week (usually the Sunday dose) for at least the first 45 days of treatment. This requires patients from the Tri Cities area to come to the clinic each and every day, except Sunday, for the first 45 days of treatment – in effect requiring them to drive 4,500 miles during the first 45 days of treatment. Tri Cities patients driving to Knoxville are required to drive approximately 9,000 miles in the first 45 days of treatment.

31. Crossroads presently has numerous patients from the Johnson City area (and the greater Tri Cities Area) that must drive 100 miles or more roundtrip to our clinic in Weaverville, North Carolina. If a clinic opened in Johnson City, Case 2:14-cv-00233-JRG-MCLC Document 15-18 Filed 06/09/14 Page 11 of 15 PageID #: 844

these patients could go to Johnson City for their methadone maintenance treatment, which would save thousands of miles of extra driving, they do now to come to clinics in North Carolina, Virginia, and elsewhere.

32. The patients from Tri-Cities who travel many miles to the nearest OTP will also highlight the need in other ways. If a Johnson City patient travels 200 miles round trip to Knoxville, he or she will also consume approximately \$30 in gas and over three hours of drive time. That is a real hardship for patients, especially new patients who must come seven days per week. Under current rules, new patients from the Tri-Cities area driving to Knoxville (the closest clinic in TN) must drive up to 9,000 miles in the first 45 days of treatment.

33. In my opinion, multiple methadone treatment clinics that I am part-owner around the Tennessee border serve patients within Johnson City and the Tri Cities Area. Based on this experience, I would estimate there are more than 1,000 opiate-addicted patients in this area that must drive more than 100 miles round trip to one of my clinics for treatment.

34. In my opinion, requiring opiate-addicted people to drive 100 miles or more back and forth to a treatment clinic constitutes denial of reasonable access to care.

35. In my opinion, there are no viable treatment options for opioid-addicted persons in the Tri Cities Area (Northeast Tennessee). This is because

there are no methadone treatment clinics which offer the following services in one location and for a much lower cost than through traditional physician-based treatment options:

36. In my opinion, opiate treatment through traditional physician-based locations is not a viable option for many patients because of cost, large time-requirements inherent in traditional medical office processes, lack of counseling services on site; stigma and embarrassment caused by close contact with the general patient population; and lack of convenient HIV/STD testing services.

37. Opiate Treatment Programs offer the lowest cost, least time-consuming to the patient; highly trained and specialized personnel; access to psychological support services on-site; and testing for illegal drugs and HIV/Tuberculosis/STDs.

NO SIGNIFICANT RISK TO THE COMMUNITY

38. Based on my personal experience treating thousands of opioid-addicted persons and, in addition, based upon reliable authorities in the field of addiction therapy, methadone patients coming to a clinic in Johnson City would pose no significant risk to the Johnson City community and the surrounding areas.

39. Based on my personal experience treating thousands of opioid-addicted persons and, in addition, based upon reliable authorities in the field of addiction

therapy, a methadone clinic operating in Johnson City will likely reduce criminal activity in Johnson City and the surrounding areas.

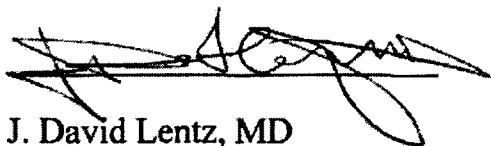
40. The testimony and opinions I provide in this Declaration are based on my personal knowledge, skill, experience, training, or education in the field of addiction therapy and, more specifically, in the field of Methadone Maintenance Treatment.

41. My testimony is based on what I consider reliable facts or data.

My testimony is the product of reliable principles and methods.

42. I have reliably applied the principles and methods to the facts of
this case as set forth in the Plaintiffs' Complaint

Executed this 15th day of April 2013.



J. David Lentz, MD